UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/500,904	02/09/2000	John B Harley	OMRF 161 CIP	3202

7590 05/08/2002

PATREA L. PABST
HOLLAND & KNIGHT LLP
ONE ATLANTIC CENTER
1201 WEST PEACHTREE STREET, SUITE 2000
ATLANTA, GA 30309-3400

EXAMINER
FOLEY, SHANON A

ART UNIT	PAPER NUMBER
1648	29

DATE MAILED: 05/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/500,904	Applicant(s) HARLEY ET AL.	
	Examiner Shanon A. Foley	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-10 and 19-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-10 and 19-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *15,28* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office action is in response to the amendment of paper no. 13, filed 7/5/01, which addresses the substantive arguments in the outstanding Office action. In that amendment, applicant cancelled claims 1-5, 11-18, 23-26 and amended claims 6-8 and 19-21. Claims 6-10 and 19-22 are under consideration.

Specification

The disclosure is objected to because of the following informalities: pages 38, 44, and 53 are blank. The table on page 62 appears to be on bond paper that has been glued into the specification under the text. Required amendments to the specification remain outstanding. Appropriate correction is required.

Drawings

The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. There are descriptions of Figures 9-11, but no drawings to accompany the descriptions. Applicant is required to furnish drawings under 37 CFR 1.81. No new matter may be introduced in the required drawings.

Applicant states that the Figures 9-11 have been cancelled. However, the specification still makes reference to the figures. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6-10 and 19-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 35 of copending Application No. 08/781,296 for reasons of record. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant states that a terminal disclaimer will be filed once allowable subject matter is indicated.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-10 and 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has amended claim 6 to recite, "predict the risk of developing lupus" and states that the terms "at risk" and "likelihood" are understood by those skilled in the art.

Applicant's amendment has been considered, but is found unpersuasive. This amendment fails to overcome issues of clarity in the claim because the "means for determining" does not correlate with the predictive step in the preamble of the claim. The factors to be assessed in the diagnostic tests in the determining a concrete statistical value correlating to the

chance of a subject contracting an autoimmune disease and with the actual diagnosis of the autoimmune disease have not been established. This fact is clearly illustrated in claim 19, affecting all dependent claims 20-22. Claim 19 still recites the relative terms "likelihood" and "at risk" to "determine **if** the differences in levels" indicate a higher or lower risk of developing autoimmune disease. This claim clearly states that the diagnostic test has not been proven to indicate the autoimmune status of an individual. This rejection affects all dependent claims.

Applicant has also amended claims 7 and 20 to more clearly indicate that different assays are being referred to.

Applicant's amendments to the claims have been considered, but fail to more clearly define the invention. It remains unclear how one could select the appropriate reagent "based upon the relative presence of the antibody" when the presence of the antibody is unknown. The claims are also unclear because it cannot be discerned how an assay is "based on" antibody presence, cellular proliferation, ect.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-10 and 19-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record.

Applicant argues that the standard for enablement is whether one skilled in the art would be able to make and use the invention and that the instant specification is fully enabled for

collecting a patient's sample and assaying them. Applicant further asserts that there was no evidence provided to support non-enablement in the previous action and that the novel peptides claimed and the observations made by the present inventors indicate patentability.

Applicant's arguments have been considered, but are unpersuasive. As discussed in the previous Office action, the specification does not teach a method or an assay that would indicate that lupus is the direct result from exposure to EBV. Although data in the specification demonstrates cross-reactivity with specific peptides between EBV and lupus, the assumption that EBV causes lupus is inconclusive. One skilled in the art would have reason to doubt that EBV is the direct cause of lupus because the prior art does not correlate exposure to EBV to developing lupus. Furthermore, satisfaction of Koch's Postulates has not been satisfied by the prior art or data presented in the instant specification. One skilled in the art would doubt that identification of a single antibody in an assay would predict the risk for developing lupus because there are other unidentified factors that may lead to autoimmune disease. Carson teaches that there are many obstacles for predicting autoimmune disease since several genes can increase susceptibility of autoimmune disease or influence immune responses to infectious agents that may trigger autoimmunity. Furthermore, even genetically identical individuals have different immune systems due to the somatic generation of immune diversity, which further indicates improbability of predicting the outcome of a changing environment. The specification does not address these concerns in the art and the instant assay and method do not take these factors into account.

Therefore, due to the lack of direction or examples conclusively correlating evidence that EBV causes autoimmune disease, the state of the art and the lack of predictability by one skilled in the art to determine the probability of development of autoimmune disease, it is maintained

that there an undue amount of experimentation would be required of one skilled in the art to practice the invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SAF
Shanon Foley/SAF
May 4, 2002

James C. Housel 5/6/02
JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600